

REMARKS

Applicants submit the Amendment in response to the Office Action mailed June 28, 2004. Claims 1-56 are withdrawn, and previously pending claims 57-62 are cancelled herein, in favor of newly presented claims 63-76, which are supported in the specification as discussed below.

Applicants thank the Examiner for the courtesy of the telephone interview held on September 1, 2004, and acknowledge the Interview Summary dated September 15, 2004. The region of SEQ ID NO:74 having homology to the Norrie disease gene is clarified and discussed further, below, in response to the rejection under 35 U.S.C. § 101.

Claims 57-62 are provisionally rejected over claims 8-13 and 28 of copending application Serial No. 10/355,716. As this is a provisional double patenting rejection, applicants request that the Examiner hold it in abeyance pending notification of allowable subject matter in either application.

Claims 57-62 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. At page 3 of the Office Action mailed June 28, 2004, the Examiner states that the argument presented in the response filed December 23, 2003 is unconvincing for two reasons: 1) the gene disclosed by Chen et al. (Nature Genetics 1(3):204-208 (1992)) is not described definitively as being the gene that causes Norrie disease, but rather as a candidate gene for that disease, and 2) one skilled in the art would not have considered SEQ ID NO:74 as encoding the Norrie gene. Reconsideration and withdrawal of this rejection are respectfully requested.

Regarding reason 1, Applicants draw the Examiner's attention to more recently published scientific literature which has removed any uncertainty about the association of the gene disclosed by Chen et al. (1992) and Norrie disease. Kim et al. (Korean J. Ophthalmol. 16(2):93-96 (2002)) and Strausberg et al. (Proc. Natl. Acad. Sci. U.S.A. 99(26):16899-16903 (2002)) each disclose a human nucleotide sequence containing the gene specifically defined as being the Norrie disease gene (GenBank Accession Nos. NM_000266 and BC029901, respectively). Tests using the BLASTN nucleotide sequence alignment algorithm (Version 2.2.9) demonstrate sequence identities of 100% and 99% for NM_000266 and BC029901, respectively, with the

nucleotide sequence disclosed by Chen et al. (1992) (GenBank Accession No. X65882). Alignments are submitted herewith as Exhibits 1 and 2.

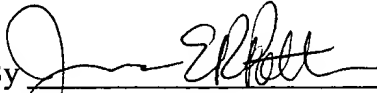
Regarding reason 2, Applicants agree with the Examiner that SEQ ID NO: 74 could not encode the full Norrie disease-associated polypeptide. However, Applicants reiterate their contention, presented on pages 3 and 4 of the amendment filed on March 18, 2002, that SEQ ID NO:74 contains significant nucleotide sequence homology with the Norrie disease gene. A test using the BLASTN nucleotide sequence alignment algorithm (Version 2.2.9) demonstrates a sequence identity of 88% between SEQ ID NO:74 and the human Norrie disease gene sequence disclosed by Chen et al. (1992) (GenBank Accession No. X65882). On page 16, lines 12-36 of the specification, the utility of polynucleotides of 50, 90 and 150 nucleotides in length is described: such polynucleotides "... are generally sufficient for unique identification of specific location in genomic DNA of a sequence coding for an unique protein. Furthermore, a 50-base pair sequence is long enough to design a PCR primer from the sequence to amplify the complete polynucleotides," (lines 31-36). Base pair numbers 1-155 of SEQ ID NO:74 contain this 88% identity with the Norrie disease gene and, with this amendment, they are now specified in the newly-submitted claims 63-76. These claims are clearly supported as discussed above.

In the Office Action mailed June 28, 2004, citing reasons discussed in the Office Action of June 4, 2002, page 2, the Examiner has also rejected claims 57-62 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. With the Supplemental Information Disclosure Statement accompanying this Amendment, Chen et al. (1992) is now part of the record. Also entered in the record are Kim et al. (2002) and Strausberg et al. (2002), which are cited above as supporting evidence that the nucleotide sequence described in Chen et al. (1992) is in fact the Norrie disease gene. The third, fourth and fifth reasons for lack of enablement rejection cited by the Examiner on page 2 of the June 4, 2002 Office Action are now obviated by this Amendment: 3) the sequence alignment of SEQ ID NO:74 and the Norrie disease gene is now in the record; 4) as explained in the immediately preceding paragraph, lines 12-36 of page 16 of the specification describe the use of SEQ ID NO:74; and 5) withdrawal of all claims pertaining to Norrie disease-specific polypeptide make moot this ground of rejection.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

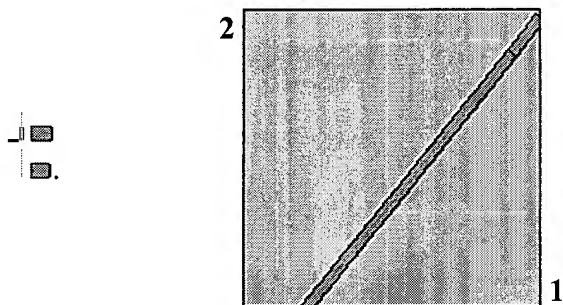
Respectfully submitted,
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Sequence 1 [gi 35016](#) Chen et al. - H.sapiens mRNA NDP **Length** 1846 (1 .. 1846)

Sequence 2 gi [20987431](#) Strausberg et al. - Homo sapiens Norrie disease (pseudoglioma), mRNA **Length** 1495 (1 .. 1495)



Score = 2777 bits (1444), Expect = 0.0
Identities = 1453/1455 (99%), Gaps = 1/1455 (0%)
Strand = Plus / Plus

Seq 1: 393 gtttttccttacaacaatgagaaaacatgtactagctgcacaccttttctatgctctccct 452
 |||||
 Seq 2: 1 gtttttccttacaacaatgagaaaacatgtactagctgcacaccttttctatgctctccct 60
 Norrie disease protein 1 M R K H V L A A S F S M L S L

Seq 1: 453 gctggtgataatgggagatacagacagtaaaacggacagctcattcataatggactcgga 512
 |||
 Seq 2: 61 gctggtgataatgggagatacagacagtaaaacggacagctcattcataatggactcgga 120
 Norrie disease protein 16 L V I M G D T D S K T D S S F I M D S D

[illegible]

Seq 1: 573 tagctcaaagatggtgctcctggccagggtgcgaggggcactgcagccaggcgtcacgctc 632
| | | | |
Seq 2: 181 tagctcaaagatggtgctcctggccagggtgcgaggggcactgcagccaggcgtcacgctc 240

| | | | | | | | | | | | | | | | | | | | | | |
|------------------------|------|---|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|---|
| Norrie disease protein | 56 | S | S | K | M | V | L | L | A | R | C | E | G | H | C | S | Q | A | S | R | S |
| Seq 1: | 633 | cgagccttttggtgtcgttcagcactgtcctcaagcaacccttcggttcctcctgtcactg | 692 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 241 | cgagccttttggtgtcgttcagcactgtcctcaagcaacccttcggttcctcctgtcactg | 300 | | | | | | | | | | | | | | | | | | |
| Norrie disease protein | 76 | E | P | L | V | S | F | S | T | V | L | K | Q | P | F | R | S | S | C | H | C |
| Seq 1: | 693 | ctgccggccccagacttccaagctgaaggcactgcggctgcgatgctcagggggcatgcg | 752 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 301 | ctgccggccccagacttccaagctgaaggcactgcggctgcgatgctcagggggcatgcg | 360 | | | | | | | | | | | | | | | | | | |
| Norrie disease protein | 96 | C | R | P | Q | T | S | K | L | K | A | L | R | L | R | C | S | G | G | M | R |
| Seq 1: | 753 | actcactgccacctaccggtacatcctctcctgtcactgcgaggaatgcaattcctgagg | 812 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 361 | actcactgccacctaccggtacatcctctcctgtcactgcgaggaatgcaattcctgagg | 420 | | | | | | | | | | | | | | | | | | |
| Norrie disease protein | 116 | L | T | A | T | Y | R | Y | I | L | S | C | H | C | E | E | C | N | S | ^^^ | |
| Seq 1: | 813 | cccgtctgtgtgtgtggcttctggatgggacaactgtagaggcagttcgaccagccaggg | 872 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 421 | cccgtctgtgtgtgtggcttctggatgggacaactgtagaggcagttcgaccagccaggg | 480 | | | | | | | | | | | | | | | | | | |
| Seq 1: | 873 | aaagactggcaagaaaagagttaaggcaaaaaaggatgcaacaattctcccgggactctg | 932 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 481 | aaagactggcaagaaaagagttaaggcaaaaaaggatgcaacaattctcccgggactctg | 540 | | | | | | | | | | | | | | | | | | |
| Seq 1: | 933 | catattctagtaataaaagactctacatgcttggtgacagagagagatactctgggaactt | 992 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 541 | catattctagtaataaaagactctacatgcttggtgacagagagagatactctgggaactt | 600 | | | | | | | | | | | | | | | | | | |
| Seq 1: | 993 | ctttgcagttcccatctcctttctctggtacaatttcttttggttcattttcagattcag | 1052 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 601 | ctttgcagttcccatctcctttctctggtacaatttcttttggttcattttcagattcag | 660 | | | | | | | | | | | | | | | | | | |
| Seq 1: | 1053 | gcattttcccccttggtctctcaatgctggttggtttccaacaattcagcattagtggga | 1112 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 661 | gcattttcccccttggtctctcaatgctggttggtttccaacaattcagcattagtggga | 720 | | | | | | | | | | | | | | | | | | |
| Seq 1: | 1113 | aaaagtgggccctcatacacaagcgtgtcaggctgtcagtgttggtgcacgctggggaa | 1172 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 721 | aaaagtgggccctcatacacaagcgtgtcaggctgtcagtgttggtgcacgctggggaa | 780 | | | | | | | | | | | | | | | | | | |
| Seq 1: | 1173 | gaattttactttggaaagtagaaaagcccagcttttctgggacatcttctgttattgttg | 1232 | | | | | | | | | | | | | | | | | | |
| Seq 2: | 781 | gaattttactttggaaagtagaaaagcccagcttttctgggacatcttctgttattgttg | 840 | | | | | | | | | | | | | | | | | | |
| Seq 1: | 1233 | atqtttttttttaccttqtcatttttqgtcctaagqttqccattqctqctaaaagqttaccqa | 1292 | | | | | | | | | | | | | | | | | | |

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Seq 2:      841  |||||atgttttttttttaccttggtcattttgggtctaaggttgccattgctgctaaaggttaccga 900
Seq 1:      1293 tttcaaagtccagataccaagcatgtggatatgttttagctacgtttactcacagccagcg 1352
Seq 2:      901  |||||tttcaaagtccagataccaagcatgtggatatgttttagctacgtttactcacagccagcg 960
Seq 1:      1353 aactgacattaaaataactaacaacagattcttttatgtgatgctggaactcttgacag 1412
Seq 2:      961  |||||aactgacattaaaataactaacaacagattcttttatgtgatgctggaactcttgacag 1020
Seq 1:      1413 ctataattattatttcagaaatgactttttgaaaagtaaaagcagcataaagaatttgtcac 1472
Seq 2:      1021 |||||ctataattattatttcagaaatgactttttgaaaagtaaaagcagcataaagaatttgtcac 1080
Seq 1:      1473 aggaaggctgtctcagataaattatggtaaaaattttgtaagggagcagacttttaaagac 1532
Seq 2:      1081 |||||aggaaggctgtctcagataaattatggtaaaaattttgtaagggagcagacttttaaagac 1140
Seq 1:      1533 ttgcacaaatacggatcctgcactgactctggaaaaggcatatatgtactagtggcatgg 1592
Seq 2:      1141 |||||ttgcacaaatacggatcctgcactgactctggaaaaggcatatatgtactagtggcatgg 1200
Seq 1:      1593 agaatgcaccatactcatgcatgcaaattagacaaccaagtatgaatctatttgtgggtg 1652
Seq 2:      1201 |||||agaatgcaccatactcatgcatgcaaattagacaaccaagtatgaatctatttgtgggtg 1260
Seq 1:      1653 tgctatagcttttag-cgtgtcacgggcatcattctctaataatccacttgtccatgtgaaa 1711
Seq 2:      1261 |||||tgctatagcttttagccgtgtcacgggcatcattctctaataatccacttgtccatgtgaaa 1320
Seq 1:      1712 catgttgccaaaatgggtggcctggcttgtcttctgaacgtttggttcaaagtgtgttttg 1771
Seq 2:      1321 |||||catgttgccaaaatgggtggcctggcttgtcttctgaacgtttggttcaaagtgtgttttg 1380
Seq 1:      1772 tcctggaggctcaaattttgagttattcccacgttttgaaataaaaagagtatattcaaa 1831
Seq 2:      1381 |||||tcctggaggctcaaattttgagttattcccacgttttgaaataaaaagagtatattcaaa 1440
Seq 1:      1832 aaaaaaaaaaaaaaaaaa 1846
Seq 2:      1441 |||||aaaaaaaaaaaaaaaaa 1455
CPU time:    0.02 user secs.    0.01 sys. secs    0.03 total secs.

Lambda      K      H
    1.33    0.621    1.12

```

Gapped

| Lambda | K | H |
|--------|-------|------|
| 1.33 | 0.621 | 1.12 |

Matrix: blastn matrix:1 -2

Gap Penalties: Existence: 5, Extension: 2

Number of Sequences: 1

Number of Hits to DB: 547

Number of extensions: 60

Number of successful extensions: 50

Number of sequences better than 10.0: 1

Number of HSP's better than 10.0 without gapping: 1

Number of HSP's gapped: 32

Number of HSP's successfully gapped: 2

Number of extra gapped extensions for HSPs above 10.0: 0

Length of Seq 1: 1846

Length of database: 11,840,914,473

Length adjustment: 26

Effective length of Seq 1: 1820

Effective length of database: 11,840,914,447

Effective search space: 21550464293540

Effective search space used: 21550464293540

Neighboring words threshold: 0

Window for multiple hits: 0

X1: 11 (21.1 bits)

X2: 26 (50.0 bits)

X3: 26 (50.0 bits)

S1: 12 (25.0 bits)

S2: 21 (41.1 bits)

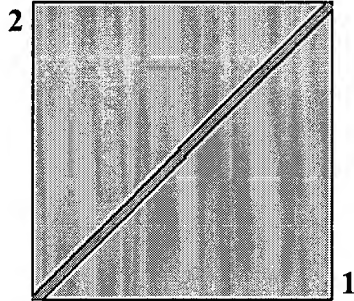
BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.9 [May-01-2004]

Match: Mismatch: gap open: gap extension:
 x_dropoff: expect: wordsize: ☐ Filter

Sequence 1 gi 35016 Chen et al. - H.sapiens mRNA NDP

Length 1846 (1 .. 1846)

Sequence 2 gi 4557788 Kim et al. - Homo sapiens Norrie disease (pseudoglioma) (NDP), mRNA **Length** 1846 (1 .. 1846)



Score = 3549 bits (1846), Expect = 0.0
 Identities = 1846/1846 (100%)
 Strand = Plus / Plus

```

Seq 1:      1      cctctctctctctccctctctctctccctctctctctccctgtgtcgcttaaacaaca 60
              |||
Seq 2:      1      cctctctctctctccctctctctctccctctctctctccctgtgtcgcttaaacaaca 60

Seq 1:     61      gtcctaacttttgtgtgttgcaaataaaaaggcaagccatgtgacagaggacagaaga 120
              |||
Seq 2:     61      gtcctaacttttgtgtgttgcaaataaaaaggcaagccatgtgacagaggacagaaga 120

Seq 1:    121      acaaaaagcatttggaagtaacaggacctctttctagctctcagaaaagtctgagaagaaa 180
              |||
Seq 2:    121      acaaaaagcatttggaagtaacaggacctctttctagctctcagaaaagtctgagaagaaa 180

Seq 1:    181      ggagccctgcgttcccctaagctgtgcagcagatactgtgatgatggattgcaagtgcaa 240
              |||
Seq 2:    181      ggagccctgcgttcccctaagctgtgcagcagatactgtgatgatggattgcaagtgcaa 240

Seq 1:    241      agagtaagacaaaaactccagcacataaaggacaatgacaaccagaaagcttcagcccgat 300
              |||
Seq 2:    241      agagtaagacaaaaactccagcacataaaggacaatgacaaccagaaagcttcagcccgat 300

Seq 1:    301      cctgccctttccttgaacgggactggatcctaggagggtgaagccatttccaatttttgt 360
              |||

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Seq 2: 301 cctgccctttccttgaacgggactggatcctaggaggtgaagccatttccaatttttgt 360

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 |||||

Seq 2: 361 cctctgcctccctctgctgttcttctagagaagtttttccttacaacaatgagaaaacat 420
 Norrie disease protein 1 M R K H

Seq 1: 421 gtactagctgcatccttttctatgctctccctgctgggtgataatgggagatacagacagt 480
 |||||

Seq 2: 421 gtactagctgcatccttttctatgctctccctgctgggtgataatgggagatacagacagt 480
 Norrie disease protein 5 V L A A S F S M L S L L V I M G D T D S

Seq 1: 481 aaaacggacagctcattcataatggactcggaccctcgacgctgcatgaggcaccactat 540
 |||||

Seq 2: 481 aaaacggacagctcattcataatggactcggaccctcgacgctgcatgaggcaccactat 540
 Norrie disease protein 25 K T D S S F I M D S D P R R C M R H H Y

Seq 1: 541 gtggattctatcagtcacccattgtacaagtgtagctcaaagatgggtgctcctggccagg 600
 |||||

Seq 2: 541 gtggattctatcagtcacccattgtacaagtgtagctcaaagatgggtgctcctggccagg 600
 Norrie disease protein 45 V D S I S H P L Y K C S S K M V L L A R

Seq 1: 601 tgcgaggggactgcagccaggcgtcacgctccgagcctttgggtgctcgttcagcactgtc 660
 |||||

Seq 2: 601 tgcgaggggactgcagccaggcgtcacgctccgagcctttgggtgctcgttcagcactgtc 660
 Norrie disease protein 65 C E G H C S Q A S R S E P L V S F S T V

Seq 1: 661 ctcaagcaacccttccgttcctcctgtcactgctgccggccccagacttccaagctgaag 720
 |||||

Seq 2: 661 ctcaagcaacccttccgttcctcctgtcactgctgccggccccagacttccaagctgaag 720
 Norrie disease protein 85 L K Q P F R S S C H C C R P Q T S K L K

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 |||||

Seq 2: 721 gcactgcggctgcgatgctcagggggcatgcgactcactgccacctaccggtacatcctc 780
 Norrie disease protein 105 A L R L R C S G G M R L T A T Y R Y I L

Seq 1: 781 tcctgtcactgcgaggaatgcaattcctgaggcccgctgctgtgtgtggcttctggatgg 840
 |||||

Seq 2: 781 tcctgtcactgcgaggaatgcaattcctgaggcccgctgctgtgtgtggcttctggatgg 840
 Norrie disease protein 125 S C H C E E C N S ^^^

Seq 1: 841 gacaactgtagaggcagttcgaccagccaggggaaagactggcaagaaaagagttaaggca 900
 |||||

Seq 2: 841 gacaactgtagaggcagttcgaccagccaggggaaagactggcaagaaaagagttaaggca 900

Seq 1: 901 aaaaaggatgcaacaattctccccgggactctgcatattctagtaataaagactctacatg 960

| | | | |
|--------|------|--|------|
| Seq 2: | 901 | aaaaaggatgcaacaattctcccgggactctgcatattctagtaataaagactctacatg | 960 |
| Seq 1: | 961 | cttggtgacagagagagataactctgggaacttctttgcagttcccatctcctttctctgg | 1020 |
| Seq 2: | 961 | cttggtgacagagagagataactctgggaacttctttgcagttcccatctcctttctctgg | 1020 |
| Seq 1: | 1021 | tacaatttcttttggttcattttcagattcaggcattttcccccttggtctcfaatgctg | 1080 |
| Seq 2: | 1021 | tacaatttcttttggttcattttcagattcaggcattttcccccttggtctcfaatgctg | 1080 |
| Seq 1: | 1081 | tttgggtttccaacaattcagcattagtgggaaaaagtggggccctcatacacaagcgtgt | 1140 |
| Seq 2: | 1081 | tttgggtttccaacaattcagcattagtgggaaaaagtggggccctcatacacaagcgtgt | 1140 |
| Seq 1: | 1141 | caggctgtcagtggttggtgcacgctggggaagaatttactttggaaagtagaaaagccc | 1200 |
| Seq 2: | 1141 | caggctgtcagtggttggtgcacgctggggaagaatttactttggaaagtagaaaagccc | 1200 |
| Seq 1: | 1201 | agcttttcctgggacatcttctgttattggtgatgttttttttaccttgtcattttggt | 1260 |
| Seq 2: | 1201 | agcttttcctgggacatcttctgttattggtgatgttttttttaccttgtcattttggt | 1260 |
| Seq 1: | 1261 | ctaagggtgccattgctgctaaagggtaccgatttcaaagtccagataccaagcatgtgg | 1320 |
| Seq 2: | 1261 | ctaagggtgccattgctgctaaagggtaccgatttcaaagtccagataccaagcatgtgg | 1320 |
| Seq 1: | 1321 | atatgttttagctacgtttactcacagccagcgaactgacattaaaataactaacaacag | 1380 |
| Seq 2: | 1321 | atatgttttagctacgtttactcacagccagcgaactgacattaaaataactaacaacag | 1380 |
| Seq 1: | 1381 | attcttttatgtgatgctggaactcttgacagctataattattattcagaaatgactttt | 1440 |
| Seq 2: | 1381 | attcttttatgtgatgctggaactcttgacagctataattattattcagaaatgactttt | 1440 |
| Seq 1: | 1441 | tgaaagtataaagcagcataaagaatttgtcacaggaaggctgtctcagataaattatggt | 1500 |
| Seq 2: | 1441 | tgaaagtataaagcagcataaagaatttgtcacaggaaggctgtctcagataaattatggt | 1500 |
| Seq 1: | 1501 | aaaattttgtaagggagcagacttttaagacttgacaaaatacggatcctgcactgact | 1560 |
| Seq 2: | 1501 | aaaattttgtaagggagcagacttttaagacttgacaaaatacggatcctgcactgact | 1560 |
| Seq 1: | 1561 | ctggaaaaggcatatatgtactagtggcatggagaatgcaccatactcatgcatgcaaat | 1620 |
| Seq 2: | 1561 | ctggaaaaggcatatatgtactagtggcatggagaatgcaccatactcatgcatgcaaat | 1620 |

Seq 1: 1621 tagacaaccaagtatgaatctatttgtgggtgtgctatagctttagcgtgtcacgggcat 1680
 |||

Seq 2: 1621 tagacaaccaagtatgaatctatttgtgggtgtgctatagctttagcgtgtcacgggcat 1680

Seq 1: 1681 cattctctaatatccacttgtccatgtgaaacatgttgccaaaatggaggcctggcttgt 1740
 |||

Seq 2: 1681 cattctctaatatccacttgtccatgtgaaacatgttgccaaaatggaggcctggcttgt 1740

Seq 1: 1741 cttctgaacgtttggttcaaatgtgttttggctcctggaggctcaaattttgagttattcc 1800
 |||

Seq 2: 1741 cttctgaacgtttggttcaaatgtgttttggctcctggaggctcaaattttgagttattcc 1800

Seq 1: 1801 cacgttttgaaataaaaaagagtatatattcaaaaaaaaaaaaaaaaaaaaaa 1846
 |||

Seq 2: 1801 cacgttttgaaataaaaaagagtatatattcaaaaaaaaaaaaaaaaaaaaaa 1846

CPU time: 0.02 user secs. 0.01 sys. secs 0.03 total secs.

Lambda K H
 1.33 0.621 1.12

Gapped
 Lambda K H
 1.33 0.621 1.12

Matrix: blastn matrix:1 -2
 Gap Penalties: Existence: 5, Extension: 2
 Number of Sequences: 1
 Number of Hits to DB: 578
 Number of extensions: 31
 Number of successful extensions: 17
 Number of sequences better than 10.0: 1
 Number of HSP's better than 10.0 without gapping: 1
 Number of HSP's gapped: 1
 Number of HSP's successfully gapped: 1
 Number of extra gapped extensions for HSPs above 10.0: 0
 Length of Seq 1: 1846
 Length of database: 11,840,914,473
 Length adjustment: 26
 Effective length of Seq 1: 1820
 Effective length of database: 11,840,914,447
 Effective search space: 21550464293540
 Effective search space used: 21550464293540
 Neighboring words threshold: 0
 Window for multiple hits: 0
 X1: 11 (21.1 bits)
 X2: 26 (50.0 bits)
 X3: 26 (50.0 bits)
 S1: 12 (25.0 bits)
 S2: 21 (41.1 bits)